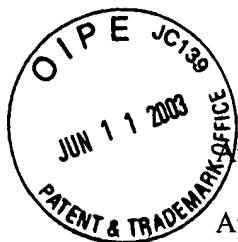


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant: Vincent Fischetti et al.

Appl. No.: 09/910,940

Group Art Unit: Unassigned

Filing Date: July 13, 2001

Examiner: Unassigned

Title: Use of Bacterial Phage Associated Lytic Enzymes to Prevent Food Poisoning

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56 and 37 CFR §1.97**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents is being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action that would be appropriate to antedate or otherwise remove as a competent reference any document that is determined to be a *prima facie* prior art reference against the claims of the present application.

The instant Information Disclosure Statement is being filed in compliance with 37 CFR §1.97(b) prior to the mailing date of the first official action, therefore, no fee is required in connection with its filing. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 08-1641.

U.S. Serial No.: 09/910,940

In re Vincent Fischetti et al.

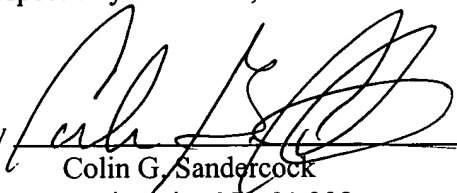
Attached as Appendix A is a list of all patents and applications filed by the present inventive entity relating to phage associated lytic enzymes and their uses. The listed U.S. patents are cited in the attached form SB/08A.

Attached herewith as Appendices 1-6 are copies of International Search Reports received in PCT applications corresponding to applications listed in Appendix A. For the Examiner's convenience, the cover sheet and claims for each of the PCT applications are also provided.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,

Date: 6.10.03

By   
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 11

**Complete if Known**

Application Number	09/910,940
Filing Date	07/13/01
First Named Inventor	Vincent Fischetti
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1	US- 6056954	05/02/00	Fischetti, et al.	
	2	US- 5997862	12/07/99	Fischetti, et al.	
	3	US- 5985271	11/16/99	Fischetti, et al.	
	4	US- 5688501	11/18/97	Merrill, et al.	
	5	US- 4742981	05/10/88	Converse	
	6	US- 2019789	11/05/35	Mahannah	
	7	US- 2763931	09/25/56	McMillan	
	8	US- 5479732	01/02/96	Burtch, et al.	
	9	US- 3465445	09/09/69	Fisher	
	10	US- 2315260	03/30/43	Lancaster	
	11	US- 5604109	02/18/97	Fischetti, et al.	
	12	US- 5260292	11/09/93	Robinson, et al.	
	13	US- 4957686	09/18/90	Norris	
	14	US- 6017528	01/25/00	Fischetti, et al.	
	15	US- 6132970	10/17/00	Stemmer	
	16	US- 3852424	12/03/74	Gaeumann, et al.	
	17	US- 6264945	07/24/01	Fischetti, et al.	
	18	US- 6254866	07/03/01	Fischetti, et al.	
	19	US- 6248324	06/19/01	Fischetti, et al.	
	20	US- 6238661	05/29/01	Fischetti, et al.	

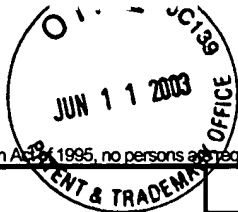
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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	21	EP-0510907 A 2 ✓	10/28/92	Agricultural & Food Res.		
	22	WO-9702351 ✓	01/23/97	CIBA Geigy AG, et al.		
	23	WO-9607329 ✓	03/14/96	Univ. Maryland		
	24	WO-9904809 ✓	02/04/99	Ambi, Inc.		
	25	FR-2357246 ✓	02/03/78	Martinez		
	26	WO-9531562 ✓	11/23/95	Quest International B.V.		
	27	EP-587541 A1 ✓	03/16/94	Tecnogen ScpA		

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Sheet 2 of 11

**Complete if Known**

Application Number	09/910,940
Filing Date	07/13/01
First Named Inventor	Vincent Fischetti
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	

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	28	US- 6056955	05/02/00	Fischetti, et al.	
	29	US- 5882631	03/16/99	Suga, et al.	
	30	US- 5741487	04/21/98	Asai, et al.	
	31	US- 6113887	09/05/00	Mori, et al.	
	32	US- 4122158	10/24/78	Schmitt	
	33	US- 3983209	09/28/76	Schmitt	
	34	US- 4885163	12/05/89	Shaar, et al.	
	35	US- 6177554	01/23/01	Woo, et al.	
	36	US- 6187757	02/13/01	Clackson, et al.	
	37	US- 5162226	11/10/92	Beachey, et al.	
	38	US- 6335012	01/01/02	Fischetti, et al.	
	39	US- 6326002	12/04/01	Fischetti, et al.	
	40	US- 6277399	08/21/01	Fischetti, et al.	
	41	US- 4062941	12/13/77	Davies	
	42	US- 5571667	11/05/96	Chu, et al.	
	43	US- 5514602	05/07/96	Brooks Jr, et al.	
	44	US- 5500350	03/19/96	Baker, et al.	
	45	US- 5384265	01/24/95	Kidwell, et al.	
	46	US- 4361537	11/30/82	Deutsch, et al.	
	47	US- 5120643	06/09/92	Ching, et al.	

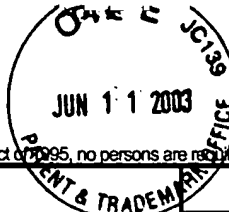
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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	48	WO-9323544 ✓	11/25/93	The University Court of the University of Glasgow		
	49	EP-0293249 A1 ✓	11/30/88	Amrad Corporation Limited		
	50	EP-0646646 A2 ✓	04/05/95	Bristol-Myers Squibb Company		
	51	EP-0359873 A1 ✓	03/28/90	The Public Health Research Inst. of the City of New York		

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Sheet 4 of 11

**Complete if Known**

Application Number	09/910,940
Filing Date	07/13/01
First Named Inventor	Vincent Fischetti
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	

**U.S. PATENT DOCUMENTS**

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		Number - Kind Code <sup>2</sup> (if known)			
	72	US- 5604110	02/18/97	Baker, et al.	
	73	US- 5294369	03/15/94	Shigekawa, et al.	
	74	US- 5372931	12/13/94	Friedman, et al.	
	75	US- 4933185	06/12/90	Wheatley, et al.	
	76	US- 5108758	04/28/92	Aliwood, et al.	
	77	US- 4713249	12/15/87	Schroder	
	78	US- 4812445	03/14/89	Eden, et al.	
	79	US- 3622677	11/23/71	Short, et al.	
	80	US- 4369308	01/18/83	Trubiano	
	81	US- 5393658	02/28/95	Olsen	
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Sheet 5 of 11

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Application Number	09/910,940
Filing Date	07/13/01
First Named Inventor	Vincent Fischetti
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	

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	82	KH Nasibulini et al; RU-2103991; Composition for treating streptococcal diseases - comprises purified concentrate of streptococcal bacteriophage, solution of quinosol, dry lanolin, albumin and vegetable oil; XP-002141110	
	83	LD Demidova et al; RU2064299; Cattle mastitis therapeutic preparation - comprises lyso: amidase of specific lytic activity and mono- and di-basic sodium phosphate(s); XP-002141111	

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First Named Inventor	Vincent Fischetti
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Examiner Name	Unassigned
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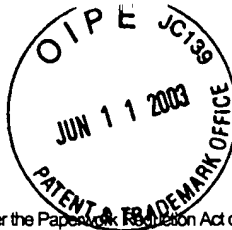
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	84	BABENKO et al. Enzymatic lysis of staphylococci in relation to their species and strain properties, 1990, Database Medline Online, US National Library of Medicine, Bethesda, MD, US, Database Accession No. 90297672 XP002170795, abstract only	
	85	BARTELL, et al., Origin of polysaccharide depolymerase associated with bacteriophage infection, Journal of Virology, March 1969, pp. 290-296, Vol. 3, No. 3	
	86	BEHNKE, et al., Cloning and expression in Escherichia coli, Bacillus subtilis and Streptococcus sanguis of a gene for staphylokinase - a bacterial plasminogen activator, Mol Gen Genet, December 1987, pp. 528-534, Vol. 210	
	87	BESSEN, et al., Chemical characterization of binding properties of opacity-associated protein II from Neisseria gonorrhoeae, Infection and Immunity, January 1987, pp. 141-147, Vol. 55, No. 1	
	88	BIZIULEVICHUS, et al., In vivo studies on lysostathin: 3. Efficacy for treatment of mastitis and superficial lesions of the udder and teats in cows, 1998, Database Biosis Online, Biosciences Information Service, Philadelphia, PA, US, Database Accession No. PREV199800492606, XP002183274, abstract only	
	89	BOIZET, et al., Cloning, expression and sequence analysis of an endolysin-encoding gene of Lactobacillus bulgaricus bacteriophage mv1, Gene, 2000, pp. 61-67, Vol. 94	
	90	CALDWELL, et al., Purification and partial characterization of the major outer membrane protein of Chlamydia trachomatis, Infection and Immunity, March 1981, pp. 1161-1176, Vol. 31, No. 3	
	91	YOUNG et al. Phages will out: strategies of host cell lysis, Trends in Microbiology, Volume 8 No. 3, March 2000, pp 120-127	
	92	CORBEL, et al., Soluble antigens obtained from influenza virus by treatment with non-ionic detergent, J Hyg., Camb., 1970, pp. 81-96, Vol. 68	
	93	CROUX, et al., Interchange of functional domains switches enzymes specificity: construction of a chimeric pneumococcal-clostridial cell wall lytic enzyme, Molecular Microbiology, 1993, pp.1019-25, Vol. 9, No. 5	
	94	DIAZ, et al., Chimeric phage-bacterial enzymes: a clue to the modular evolution of genes, Proc. Natl. Acad. Sci. USA, October 1990, pp. 8125-8129, Vol. 87	

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Application Number	09/910,940
Filing Date	07/13/01
First Named Inventor	Vincent Fischetti
Group Art Unit	Unassigned
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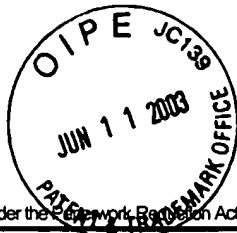
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	95	DIAZ, et al., Chimeric pneumococcal cell wall lytic enzymes reveal important physiological and evolutionary traits, Journal of Biological Chemistry, March 25, 1991, pp. 5464-5471, Vol. 266, No. 9	
	96	DIXON, et al., Lysostaphin: an enzymatic approach to staphylococcal disease. III. Combined lysostaphin-methicillin therapy of established staphylococcal abscesses in mice, The Yale Journal of Biology and Medicine, August 1968, pp. 62-68, Vol. 41, No. 1	
	97	FISCHETTI, et al., Size variation of the M protein in group A streptococci, Journal of Exp. Med., June 1, 1985, pp. 1384-1401, Vol. 161, No. 6	
	98	GARCIA, et al., Bacteriophages of Streptococcus pneumoniae: A molecular approach, Microbial Drug Resistance, Summer 1997, pp. 165-176, Vol. 3, No. 2	
	99	GARCIA, et al., Cloning, purification and biochemical characterization of the pneumococcal bacteriophage Cp-1 lysin, Journal of Virology, August 1987, pp. 2573-2580, Vol. 61, No. 8	
	100	GARCIA, et al., Modular organization of the lytic enzymes of streptococcus pneumoniae and its bacteriophages, Gene, 1990, pp. 81-88, Vol. 86	
	101	GERARDY-SCHANN, et al., Molecular cloning and functional expression of bacteriophage PK1E-encoded endoneuraminidase Endo NE, Molecular Microbiology, May 1995, pp. 441-450, Vol. 16, No. 3	
	102	GOLDBERG, et al., Studies in experimental staphylococcal endocarditis in dogs, Antimicrobial Agents and Chemotherapy, 1967, pp. 45-53	
	103	HARRISON, et al., Lysostaphin in experimental renal infections, Journal of Bacteriology, February 1967, pp. 520-524, Vol. 93, No. 2	
	104	HARRISON, et al., Therapeutic activity of lysostaphin in experimental staphylococcal infections, Canadian Journal of Microbiology, January 1967, pp. 93-97, Vol. 13, No. 1	
	105	HAYASHI, et al., Effects of N-Acetylmuramidase from Streptomyces rutgersensis H-46 as a food preservative, Agric. Biol. Chem., December 1989, pp. 3173-3177, Vol. 53, No. 12	

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Sheet 8 of 11

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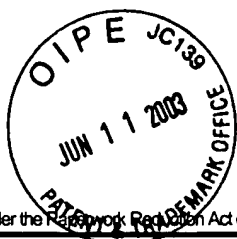
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	106	HAYASHIDA, et al., Further characterization of PL-1 phage associated N-acetylmuramidase of Lactobacillus casei, Journal of General Microbiology, May 1987, pp. 1343-1349, Vol. 133, No. 5	
	107	HIGUCHI, et al., Transfection of streptococcus sanguis by phage deoxyribonucleic acid isolated from streptococcus mutans, Infection and Immunity, March 1977, pp. 945-949, Vol. 15, part 3	
	108	HUAN, et al., Methicillin-resistant staphylococcus aureus infection and its treatment in burned patients, Chinese Journal of Surgery, 1994, Vol. 32, No. 4, abstract	
	109	HUGHEY, et al., Antimicrobial activity of lysozyme against bacteria involved in food spoilage and food-borne disease, Applied and Environmental Microbiology, September 1987, pp. 2165-2170, Vol. 53, No. 9	
	110	KOHLER, Systemic therapy with aerosols Aerosols in Medicine: Principles, Diagnosis and Therapy, 1993, Elsevier Science Publishers, pp. 303-319	
	111	LAWMAN, et al., Molecular cloning of the extracellular endodextranase of streptococcus salivarius, Journal of Bacteriology, December 1991, pp. 7423-7428, Vol. 173, No. 23	
	112	LOESSNER, et al., Evidence for a holin-like protein gene fully embedded out of frame in the endolysin gene of staphylococcus aureus bacteriophage 187, Journal of Bacteriology, August 1999, pp. 4452-4460, Vol. 181, No. 15	
	113	LOESSNER, et al., Modified listeria bacteriophage lysin genes (ply) allow efficient overexpression and one - step purification of biochemically active fusion proteins, Applied and Environmental Microbiology, August 1996, pp. 3057-3060, Vol. 62, No. 8	
	114	LOPEZ, et al., Architecture and domain interchange of the pneumococcal cell wall lytic enzymes, Genetics of Streptococci, Enterococci and Lactococci, Developments in Biological Standardization, 1995, pp. 273-281, Vol. 85	
	115	LOPEZ, et al., The pneumococcal cell wall degrading enzymes a modular design to create new lysins, Microbial Drug Resistance, November 2, 1997, pp. 199-211, Vol. 3, No. 2	
	116	MARTIN, et al., Functional analysis of the two-gene lysis system of the pneumococcal phage Cp-1 in homologous and heterologous host cells, Journal of Bacteriology, January 1998, pp. 210-217, Vol. 180, No. 2	

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 9 of 11

**Complete if Known**

Application Number	09/910,940
Filing Date	07/13/01
First Named Inventor	Vincent Fischetti
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	

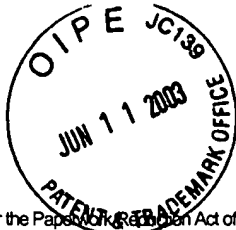
**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	117	MUKHLIS, et al., Characterization and Immunogenicity of HSV-1 antigens obtained following zwitterionic detergent treatment; Vaccine, September 1986, pp. 191-196, Vol. 4	
	118	NELSON, et al., Prevention and elimination of upper respiratory colonization of mice by group A streptococci by using a bacteriophage lytic enzyme, PNAS, March 27, 2001, pp. 4107-4112, Vol. 98, No. 7	
	119	NELSON, et al., Selective and rapid killing of group A streptococci using a muralytic enzyme, Database Biosis Online, Biosciences Information Service, Philadelphia, PA, US and abstracts of the General Meeting of the American Society for Microbiology, 2000, pp. 32-33	
*	120	OKI, et al., Functional and structural features of the holin HOL protein of the Lactobacillus plantarum phage analysis in escherichia coli system, Gene, 1997, pp. 137-145, Vol. 197	
	121	OKUHARA, et al., Preparation of group A streptococcal cell membranes by treatment with group C streptococcus phage - associated lysin, Annales Paediatrici Japonici, June 1983, pp. 10-19, Vol. 29, No. 2	
	122	PATTON, et al., Routes of delivery: case studies, Pulmonary delivery of peptides and proteins for systemic action, Advanced Drug Delivery Reviews, 1992, pp. 179-196, Vol. 8	
	123	POLAK, et al., In vitro activity of recombinant lysostaphin-antibiotic combinations toward methicillin-resistant staphylococcus aureus, Diagn. Microbiol. Infect. Dis., 1993, pp. 265-270, Vol. 17	
	124	RAINA, Purification of streptococcus group C bacteriophage lysin, Journal of Bacteriology, January 1981, pp. 661-663, Vol. 145, No. 1	
	125	RONDA, et al., Infection of streptococcus oralis NCTC 11427 by pneumococcal phages, FEMS Microbiology Letters, 1989, pp. 187-192, Vol. 65	
	126	SANZ, et al., Construction of a multifunctional pneumococcal murein hydrolase by module assembly, Eur. J. Biochem., February 1, 1996, pp. 601-605, Vol. 235, No. 3	
	127	SATO, et al., Partial characterization of n - Butanol - solubilized rejection - type antigens of syngeneic murine colon tumors, JNCI, April 1985, Vol. 74, No. 4	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



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**INFORMATION DISCLOSURE  
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Sheet 10 of 11

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Application Number	09/910,940
Filing Date	07/13/01
First Named Inventor	Vincent Fischetti
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	

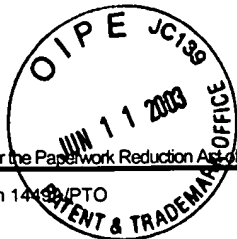
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	128	SHEEHAN, et al., Analysis of the catalytic domain of the lysin of the lactococcal bacteriophage Tuc2009 by chimeric gene assembling; FEMS Microbiology Letters, 1996, pp. 23-28, Vol. 140	
	129	SHEEHAN, et al., The lytic enzyme of the pneumococcal phage Dp-1: A chimeric lysin of intergeneric origin, Molecular Microbiology, 1997, pp. 717-725	
	130	WITTE, et al., Characterization of escherichia coli lysis using a family of chimeric E-L genes, FEMS Microbiology Letters, 1998, pp. 159-167, Vol. 164	
	131	YARNALL, et al., Isolation and partial characterization of a type II Fc receptor from a group A streptococcus, Molecular and Cellular Biochemistry, 1986, pp. 57-66, Vol. 70	
	132	CISANI, et al., High-level potentiation of lysostaphin anti-staphylococcal activity by lysozyme, Antimicrobial Agents and Chemotherapy, April 1982, pp. 531-535, Vol.21, No. 4	

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Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 11 of 11

**Complete if Known**

Application Number	09/910,940
Filing Date	07/13/01
First Named Inventor	Vincent Fischetti
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	133	US-5605793	02/25/97	Stemmer	
	134	US- 6355477	03/12/02	Fischetti et al	
	135	US- 6331405	12/18/01	Rambukkana et al	
	136	US- 6190659	02/20/01	Pancholi et al	
	137	US- 5985654	11/16/99	Fischetti et al	
	138	US- 5842314	11/24/98	Scott et al	
	139	US- 5910441	06/08/99	Rocha et al	
	140	US- 5786205	07/28/98	Fischetti et al	
	141	US- 5976792	11/02/99	Cheung et al	
	142	US- 5821088	10/13/98	Darzens et al	
	143	US- 5723303	03/03/98	Fischetti et al	
	144	US- 5643767	07/01/97	Fischetti et al	
	145	US- 5707822	01/13/98	Fischetti et al	
	146	US- 5616686	04/01/97	Fischetti et al	
	147	US- 5604109	02/18/97	Fischetti et al	
	148	US- 5587288	12/24/96	Cheung et al	
	149	US- 5556944	09/17/96	Fischetti et al	
	150	US- 5352588	10/04/94	Fischetti et al	
	151	US- 5968763	10/19/99	Fischetti et al	
	152	US- 4784948	11/15/88	Scott et al	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	153	WO 03/024410 A2	03/27/03	Fischetti et al		

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<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

# Appendix A

<b>Serial No.</b>	<b>Filing Date</b>	<b>Patent No.</b>	<b>Issue Date</b>
07/621,716	June 18, 1984	4,784,948	November 15, 1988
09/257,025	February 25, 1999	6,017,528	January 25, 2000
09/257,026	February 25, 1999	5,985,271	November 16, 1999
09/333,538	June 15, 1999		
09/395,636	September 14, 1999	6,056,954	May 2, 2000
09/395,637	September 14, 1999	6,056,955	May 2, 2000
09/482,992	January 14, 2000	6,264,945	July 24, 2001
09/497,495	April 18, 2000	6,238,661	May 29, 2001
09/560,650	April 28, 2000		
09/653,690	September 1, 2000	6,254,866	July 3, 2001
09/654,482	September 1, 2000	6,399,097	June 4, 2002
09/654,483	September 1, 2000	6,423,299	July 23, 2002
09/654,484	September 1, 2000		
09/671,878	September 28, 2000	6,432,444	August 13, 2002
09/671,879	September 28, 2000	6,248,324	June 19, 2001
09/671,880	September 28, 2000	6,406,692	June 18, 2002
09/671,881	September 28, 2000	6,428,784	August 6, 2002
09/671,882	September 28, 2000	6,277,399	August 21, 2001
09/671,990	September 28, 2000	6,326,002	December 4, 2001
09/671,991	September 28, 2000	6,399,098	June 4, 2002
09/671,992	September 28, 2000	6,335,012	January 1, 2002
09/703,164	November 2, 2000		
09/703,582	November 2, 2000		
09/703,583	November 2, 2000		
09/703,584	November 2, 2000		
09/703,585	November 2, 2000		
09/703,586	November 2, 2000		
09/703,587	November 2, 2000		
09/703,588	November 2, 2000		
09/703,595	November 2, 2000		
09/703,656	November 2, 2000		
09/703,685	November 2, 2000		

## Appendix A

<b>Serial No.</b>	<b>Filing Date</b>	<b>Patent No.</b>	<b>Issue Date</b>
09/703,686	November 2, 2000		
09/703,739	November 2, 2000		
09/703,740	November 2, 2000		
09/704,148	November 2, 2000		
09/704,149	November 2, 2000		
09/752,731	January 3, 2001		
09/844,435	April 30, 2001		
09/846,688	May 2, 2001		
09/866,106	May 25, 2001		
09/908,737	July 19, 2001		
09/910,940	July 13, 2001		
09/932,460	August 20, 2001		
09/960,472	September 21, 2001		
10/012,032	December 11, 2001		
10/067,979	February 8, 2002		
10/067,991	February 8, 2002		
10/067,995	February 8, 2002		
10/083,142	February 27, 2002		
10/083,462	February 27, 2002		
10/104,488	March 25, 2002		
10/105,075	March 25, 2002		
10/105,076	March 25, 2002		
10/135,824	May 1, 2002		
10/135,825	May 1, 2002		
10/135,826	May 1, 2002		
10/135,851	May 1, 2002		
10/145,604	May 14, 2002		
10/176,375	June 21, 2002		
10/176,376	June 21, 2002		
10/176,403	June 21, 2002		
10/176,405	June 21, 2002		
10/219,250	August 16, 2002		

## Appendix A

<b>Serial No.</b>	<b>Filing Date</b>	<b>Patent No.</b>	<b>Issue Date</b>
10/219,251	August 16, 2002		
10/252,031	September 23, 2002		
60/324,089	September 24, 2001		
60/380,875	May 17, 2002		